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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,745	04/09/2007	Yigal M. Pinto	BYG-101	2559

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GOODWIN PROCTER LLP
PATENT ADMINISTRATOR
53 STATE STREET
EXCHANGE PLACE
BOSTON, MA 02109-2881

EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
02/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentBos@goodwinprocter.com
hmcpeake@goodwinprocter.com
glenn.williams@goodwinprocter.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,745	PINTO, YIGAL M.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,14 and 21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,14 and 21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed October 9, 2009 is acknowledged and has been entered. Currently, claims 1, 2, 5, 6, 14, and 21-33 are pending and under examination.

Withdrawn rejections

All rejections of claims not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5, 6, 14, and 21-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a subject at risk of developing heart failure and a method for identifying a subject at risk of developing congestive heart failure comprising detecting the level of galecting-3 in a biological sample from a human subject and comparing the level of galectin-3 to a standard level indicative of risk of developing heart failure or congestive heart failure, does not reasonably provide enablement for identifying a subject at risk of developing any and all hypertensive end organ damage or complications of hypertensive end organ damage or complications of heart failure or complications of congestive heart failure.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re W*ands USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to methods for identifying a subject at risk of developing hypertensive end organ damage or complications of hypertensive end organ damage, complications of heart failure and complications of congestive heart failure by detecting the level of galectin-3 to a standard indicative of risk of developing hypertensive end organ damage, complications of hypertensive end organ damage, complications of heart failure or complications of congestive heart failure.

The specification fails to teach identifying a subject at risk of developing any and all hypertensive end organ damage by detecting the level of galectin-3 in the human subject and comparing to a standard that is indicative of risk of developing hypertensive end organ damage. The specification also fails to teach identifying a subject at risk of developing complications of hypertensive end organ damage, complications of heart

failure and complications of congestive heart failure. McCowan et al (Hypertensive Emergencies, emedicine, 2009, pages 1-23) discloses that hypertensive end organ damage can occur in central nervous system, cardiovascular system and renal system (e.g. pgs 1-3). Luft et al (Hypertension, 1999, 33 pages 212-218) discloses that hypertensive end organ damage occurs in the renal system (e.g. abstract, p. 213). Liu et al (Journal of biological chemistry, Vol 284, No. 23, 2009, pgs 15564-15572) teaches that hypertensive end organ damage can be characterized by renal vasoconstriction (e.g. p. 15569). The examples of the specification are limited to identifying a subject at risk of developing heart failure and congestive heart failure by detecting the level of galectin-3 in the human subject and comparing to a standard indicative of heart failure or a standard indicative of congestive heart failure. The specification fails to provide a nexus or correlation of the level of galectin-3 to any other hypertensive end organ damage other than that of heart failure or congestive heart failure. Further, the specification fails to provide examples, data or guidance on the complications of hypertensive end organ damage, complications of heart failure or complications of congestive heart failure. The specification does not provide a nexus or correlation of galectin-3 levels in subjects to complications of hypertensive end organ damage, complications of heart failure or complications of congestive heart failure. The currently broadly recited claims do not limit the hypertensive end organ damage, the complications of hypertensive end organ damage, complications of heart failure or complications of congestive heart failure. Also, as indicated by the prior art it is known that hypertensive end organ damage occurs in many systems in a subject and the prior

art nor the current specification provides a nexus or correlation of galectin-3 to such systems as the renal or neurological systems or to any other condition other than heart failure and congestive heart failure. At best identification of a subject at risk of developing heart failure or congestive heart failure can be determined by detecting the level of galectin-3 in a biological sample from a human subject and comparing the level of the galectin-3 to a standard level indicative of risk of heart failure or congestive heart failure. Thus, such is not seen as sufficient to support the breath of the claims and one skilled in the art cannot practice the claimed invention without undue experimentation, because in order to have a high level of predictability, one skilled in the art would have to know that all hypertensive end organ damage is correlated with galectin-3 levels and would also have to know the complications of hypertensive end organ damage, complications of heart failure, complications of congestive heart failure and that all the complications are correlated with galectin-3 levels.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 5, 6, 14, and 21-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting “complications of hypertensive end organ damage”. There is no definition provided for the phrase in the specification nor is

there any guidance on what the phrase encompasses. Therefore, one of ordinary skill would not be reasonably apprised of the scope of the invention.

Claim 21 is vague and indefinite in reciting “complications of congestive heart failure”. There is no definition provided for the phrase in the specification nor is there any guidance on what the phrase encompasses. Therefore, one of ordinary skill would not be reasonably apprised of the scope of the invention. See also deficiencies found in claims 25, 29 and 31.

Claim 23 is vague and indefinite in reciting “complications of heart failure”. There is no definition provided for the phrase in the specification nor is there any guidance on what the phrase encompasses. Therefore, one of ordinary skill would not be reasonably apprised of the scope of the invention.

Claim 26 is vague and indefinite because it is unclear how a standard level based on healthy subjects is indicative of risk. Claim 23 from which claim 26 depends requires the "a standard level indicative of risk". Therefore, it is unclear how a standard which is derived from healthy subjects that would not be at risk is indicative of risk.

Claim 32 is vague and indefinite because it is unclear how a standard level based on healthy subjects is indicative of risk. Claim 29 from which claim 32 depends requires the "a standard level indicative of risk". Therefore, it is unclear how a standard which is derived from healthy subjects that would not be at risk is indicative of risk.

Response to Arguments

4. Applicant's arguments filed 10/09/09 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/

Examiner, Art Unit 1641

/Melanie Yu/
Primary Examiner, Art Unit 1641